

K050494
510(K) SUMMARY

APR 13 2005

**COMPLETE® Moisture PLUS™
Multi-Purpose Disinfecting Solution**

This summary uses the format provided in 21 CFR 807.92:

(a)(1) **Submitter:** Peter Xu
Regulatory Affairs Professional
Advanced Medical Optics
1700 E. St. Andrew Place
Santa Ana, CA 92799-5162

Phone: (714) 247-8592
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Email: peter.xu@amo-inc.com

Summary Prepared: February 2005

(a)(2) **Device Trade Name:** COMPLETE® MoisturePLUS™
Multi-Purpose Disinfecting Solution

Device Common Name: Soft (Hydrophilic) Contact Lens Solution

Device Classification/Panel: Class II (Special Controls)/Ophthalmic Device

Device Classification Names: Accessories to Contact Lens Solution (86LPN)

(a)(3) **Identification of Predicate Device**

COMPLETE® MoisturePLUS™ Multi-Purpose Disinfecting Solution is the same as the currently-marketed multipurpose solution.

(a)(4) **Device Description**

COMPLETE® MoisturePLUS™ Multi-Purpose Disinfecting Solution is a sterile, isotonic, buffered, solution containing lubricants, preservatives, buffers, surfactants, ancillary ingredients, and purified water.

The product is a clear, colorless solution packaged in plastic bottles with controlled dropper tips.

(a)(5) **Intended Use (Indications for Use)**

COMPLETE® MoisturePLUS™ Multi-Purpose Disinfecting Solution is used for chemical disinfection, cleaning, rinsing, storing, protein removal and conditioning of soft (hydrophilic) contact lenses. There are no changes to the indications for use.

(a)(6) **Comparison of Technological Characteristics**

The technological characteristics of the product remain the same.

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COMPLETE® MoisturePLUS™ Multi-Purpose Disinfecting Solution

February 2005

(b)(1) Discussion of Microbiological Studies

COMPLETE® MoisturePLUS™ Multi-Purpose Disinfecting Solution was evaluated for microbiological efficacy using the stand-alone procedure for disinfecting products outlined in FDA's Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products, issued May 1, 1997. The product meets primary criteria for disinfection of contact lenses against bacteria, yeast and mold. Therefore, COMPLETE® MoisturePLUS™ Multi-Purpose Solution may be labeled as a "disinfecting" solution.

Other preclinical safety and efficacy criteria were established in a prior file.

(b)(2) Clinical

Clinical safety and acceptability of COMPLETE® MoisturePLUS™ Multi-Purpose Disinfecting Solution was established in a prior file.

(b)(3) Conclusions Drawn from Data Supporting Equivalence Determination

The safety, efficacy and performance of COMPLETE® MoisturePLUS™ Multi-Purpose Disinfecting Solution are substantially equivalent to other contact lens care multipurpose disinfecting solutions currently on the market.



APR 13 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Advanced Medical Optics
C/O Peter Xu
Regulatory Affairs Professional
1700 E. St. Andrew Place
Santa Ana, CA 92799-5162

Re: K050494

Trade/Device Name: COMPLETE® MoisturePLUS™ Multi-Purpose Disinfecting Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: February 24, 2005
Received: February 28, 2005

Dear Mr. Xu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Peter Xu

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "David M. Whipple". The signature is fluid and cursive, with a large initial "D" and "W".

David M. Whipple
Acting Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510(k) NUMBER:
(IF KNOWN):

K050494

DEVICE NAME:

COMPLETE® MoisturePLUS™
Multi-Purpose Disinfecting Solution

INDICATIONS FOR USE:

COMPLETE® MoisturePLUS™ Multi-Purpose Disinfecting Solution is indicated for the care of soft (hydrophilic) contact lenses. Use this product, as recommended by your eye care practitioner, to:

- Chemically (NOT HEAT) Disinfect
- Clean
- Rinse
- Store
- Remove Protein
- Condition

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use X _____
(Optional Format 1-2-96)

Karen W. Burk

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K050494